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Document Control Office (7407M)
Office of Pollution Prevention and Toxics
Environmental Protection Agency 1200
Pennsylvania Avenue N.W.
Washington, D.C. 20460-0001

Attn. Docket Number EPA-HQ-OPPT-2016-0725

**Re: Comments on the Scope of the Risk Evaluation, and on EPA's
Planned Problem Formulation, for C.I. Pigment Violet 29
(Anthra[2,1,9-def;6,5,10-d'e'f']diisoquino-
line1,3,8,10(2H,9H)tetrone), Chemical Abstracts Service No.
81-33-4**

Dear Sir or Madam:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") in response to EPA's request for comments on the draft Scope of the Risk Evaluation Assessment for C.I. Pigment Violet 29 (Anthra[2,1,9-def;6,5,10-d'e'f'] diisoquinoline-1,3,8,10(2H,9H)tetrone), Chemical Abstracts Service No. 81-33-4, EPA Document #740-R1-7011 (June 2017) (the "Scope Document") and EPA's planned problem formulation for C.I. Pigment Violet 29.¹

The CPMA is an industry trade association representing small, medium and large color pigments manufacturing companies. In addition, the Association represents color pigments manufacturers that sell pigments and certain colored products, and suppliers of intermediates and other chemicals products that serve color pigments manufacturers. The Association provides advocacy programs in support of the color pigments industry on matters pertaining to the environment, health, safety issues and trade. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, color cement products, textiles, cosmetics and artists' colors.

EPA seeks information that could be useful in its conduct of the problem formulation phase of the risk evaluation of C.I. Pigment Violet 29 under the Toxic Substances Control Act ("TSCA"), as amended by the Lautenberg Chemical Safety Act.

¹ 82 Fed. Reg. 31592 (July 7, 2017).

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As explained below, based on available summaries of toxicity studies, structural analog relationships with other similar pigments, and experience in use over decades, C.I. Pigment Violet 29 does not pose any known hazard in any reasonably foreseeable use or misuse, and therefore cannot present an unreasonable risk of harm actionable under TSCA. Had C.I. Pigment Violet 29 undergone the prioritization process, EPA would have recognized that C.I. Pigment Violet 29 is not likely to present an unreasonable risk of harm to health or the environment, and thus should be classified as a low priority for further evaluation. EPA can and should reach that conclusion now, and focus its limited TSCA regulatory efforts and resources on other substances which may pose unreasonable risk.

In the interests of completeness, CPMA also offers comments below regarding the reference in the Scope Document to C.I. Pigment Violet 29 as a “trade name,” the best source for information on physical/chemical data attributes of the substance, the regulatory status of the substance under other U.S. and Canadian regulatory regimes, the Scope Document’s discussion of foreseeable uses, and the bibliography.

I. The Scope Document and the Record for the Risk Evaluation of C.I. Pigment Violet 29 Do Not Provide Any Evidence of a Hazard Associated with C.I. Pigment Violet 29, and Thus No Further Risk Evaluation Is Justified

As discussed below, the profile of C.I. Pigment Violet 29 presented in the Scope Document does not justify further evaluation because C.I. Pigment Violet 29 does not exhibit any actual or potential hazard – and thus it cannot present an unreasonable risk – to human health or the environment. The Scope Document reaches this conclusion regarding carcinogenicity and ecological toxicity. While it refers to non-cancer human health hazards, it presents no documentation of such hazards. I will address each category in turn.

A. Carcinogenicity

CPMA supports EPA’s conclusion that C.I. Pigment Violet 29 does not pose a likely carcinogenic hazard based on its chemical structure and predicted characteristics. EPA states:

Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet

29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely.¹

This leads EPA to conclude that “EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29.” *Id.* Decades of manufacture and use in numerous applications without reported incident support this conclusion.

B. Ecological Toxicity

CPMA also supports EPA’s analysis of the toxicity of C.I. Pigment Violet 29 to aquatic life or the environment, which states:

Based on these fate properties, Pigment Violet 29 is expected to be highly persistent (environmental half-life ($t_{1/2}$) greater than 6 months) and have low bioaccumulation potential ($BCF/BAF < 1,000$).²

Toxicological data are available in ECHA [‘European Chemical Agency’], although no hazards have been identified in ECHA for Pigment Violet 29. ECHA provides ecotoxicology data for fish (acute), aquatic invertebrates (acute), aquatic plants/cyanobacteria and unidentified microorganisms. As noted in Section 2.3.1, Pigment Violet 29 is not expected to degrade in the environment and so at this time there are no aquatic concerns for environmental degradation products for Pigment Violet 29.³

CPMA agrees with the Scope Document regarding the persistence of C.I. Pigment Violet 29 and that C.I. Pigment Violet 29 does not, by its nature, bioaccumulate or bioconcentrate. ECHA robust study summaries indicate that C.I. Pigment Violet 29 does not show any toxicity to aquatic organisms at saturation in the water column.

Incidentally, EPA identified aquatic toxicity as the original reason for placing C.I. Pigment Violet 29 on the EPA Work Plan.⁴ EPA’s contrary conclusion above, based on the more complete information contained in the ECHA data summaries, thus confirms that C.I. Pigment Violet 29 should never have been placed on the Work Plan.

C. Non-Cancer Human Health Hazards

¹ Scope Document, p.29.

² Scope Document, p.25.

³ *Id.*

⁴ See EPA, TSCA Work Plan for Chemicals Assessments: 2014 Update (Oct. 2014), Table at 2. ⁶ Scope Document, p.9.

The Scope Document does not identify a non-cancer health hazard which could result from exposure to C.I. Pigment Violet 29 warranting further evaluation. EPA indicates in the Executive Summary of the Scope Document that information exists which substantiates a health hazard warranting the on-going risk assessment. EPA states:

Human health hazards of Pigment Violet 29 have been identified by EPA previously and include acute toxicity, eye irritation, skin irritation, skin sensitization, repeated-dose toxicity, and reproductive/developmental toxicity, all of which EPA expects to consider in the scope of the TSCA risk evaluation.⁶

Similarly, Section 2.4 of the Scope Document also refers to unidentified study information which it asserts substantiates the need for the risk assessment, stating in part:

For scoping, EPA conducted comprehensive searches for data on hazards of Pigment Violet 29, as described in Strategy for Conducting Literature Searches for Pigment Violet 29: Supplemental File for the TSCA Scope Document (EPA-HQ-OPPT-2016-0725). Based on initial screening, EPA expects to consider the hazards of Pigment Violet 29 identified in this scope document.⁵

These statements do not provide a reference or other information substantiating a hazard associated with C.I. Pigment Violet 29. The following statement provides EPA's only specific discussion regarding available non-cancer health effects for C.I. Pigment Violet 29:

2.4.2.1 Non-Cancer Hazards

Study summaries of the animal toxicity data for Pigment Violet 29 acute toxicity, skin and eye irritation, skin sensitization, repeated-dose systemic toxicity and reproductive/developmental toxicity. EPA expects to consider all of these studies in the risk evaluation.⁶

Based on review of scope documents for other substances, such as 1,4, Dioxane, this section of the Scope Document should contain reference information substantiating known health effects and the need to undertake the risk assessment for Violet 29. It does not. Nor does the Bibliography prepared for this substance – *see id.* at 89 (“No *on topic* human health references.”). Nor is CPMA aware of any such documentation. We also note that, in the 2014 Update to the TSCA Work Plan, EPA clarified that it was listing Violet 29 “based solely on environmental toxicity.”⁷ The Scope Document contains no discussion explaining the need for reevaluation of this conclusion.

⁵ *Id.*, p.28.

⁶ *Id.*, p.29. (sic – the 1st sentence is incomplete).

⁷ *See* EPA, TSCA Work Plan for Chemicals Assessments: 2014 Update (Oct. 2014), Table at 2.

For all these reasons, no further risk evaluation is warranted on the basis of non-cancer health effects.

D. Conclusion Regarding Human and Ecological Toxicity Information

Neither EPA nor anyone else has ever substantiated any concern for health or ecological effects resulting from exposure to C.I. Pigment Violet 29. Since there is no known hazard from exposure to C.I. Pigment Violet 29, there is no reason to engage in the extensive analysis of the reasonably foreseeable commercial uses for C.I. Pigment Violet 29 described in the Scope Document.

Based on the discussion above, EPA's statements regarding the contents and purpose of scope documents, and a review of the relevant toxicological information described in the CPMA comments of March 15, 2017, we wish to again emphasize that:

The lack of hazard – posed by C.I. Pigment Violet 29 is crucial to any risk assessment of the substance. As EPA is well aware, the LCSA required the Agency to begin its initial ten risk evaluations without first conducting the prioritization process that the LCSA otherwise requires as a precondition of a risk evaluation. Had EPA been free to conduct such a prioritization regarding C.I. Pigment Violet 29, CPMA is confident that EPA would have concluded it was a low priority for risk evaluation.”⁸

The Scope Document does not present any health or environmental information that might lead to a different conclusion now.

II. Additional Comments on the Scope Document and the Docket

A. Pigment Nomenclature

Regarding the use of the Colour Index Name C.I. Pigment Violet 29, the Executive Summary states:

“Pigment Violet 29 is a trade name used in sales of products containing Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone and should not be considered as an alternative technical or specific chemical name for Anthra[2,1,9-def:6,5,10-d'e'f'] diisoquinoline- 1,3,8,10(2H,9H)-tetrone.”¹¹

⁸ See CPMA Comments to Wendy Cleland-Hamnett (March 13, 2017), Docket No. EPA-HQOPPT-2016-0725-0006, p.2. (“March 13, 2017 Comments”). ¹¹ Scope Document, p.8.

This statement does not appropriately describe the Colour Index name or nomenclature. The name “C.I. Pigment Violet 29” is a Colour Index Name assigned, copyrighted and maintained by the Society of Dyers and Colourists and the American Association of Textile Colorists and Chemists. The Colour Index Name is not a tradename. The Colour Index is an international standard and classification system describing essential colorants which comprise commercial dyes and pigments. As noted in our March 13, 2017 Comments, the Colour Index Name describes the commercial dye or pigment in international commerce. It does not describe crude products or unrefined intermediates.⁹

B. Physical/Chemical Attributes of C.I. Pigment Violet 29

The Scope Document cites numerous physical attributes of C.I. Pigment Violet 29 based solely upon estimates produced by computer models. For example, the flash point calculation shown cites a value of 314°C (estimated), citing ACD (2011). This value is not in agreement with the estimated melting point of 350°C (estimated) provided in U.S. EPA (2012b).¹⁰ Similarly, the reference Jaffe (2004) is imprecise, as it refers to the EPA Health and Environmental Research Online database, and then to the Encyclopedia of Chemical Technology, without an indication of chapter or page(s) that are relevant.¹¹

Since there is available testing data for many of the relevant chemical physical attributes of C.I. Pigment Violet 29 in the summaries provided in the REACH Dossier and the information provided in the HPV submission from CPMA, EPA should use this information to inform its analysis. Of particular relevance to this assessment, C.I. Pigment Violet 29 has a measured solubility of 0.01 mg/L.¹² Due to its low solubility in water and octanol, C.I. Pigment Violet 29 does not bioaccumulate and does not exhibit any toxicologically significant attributes.¹³

C. U.S. and International Laws and Regulation of C.I. Pigment Violet 29

According to the Consumer Product Safety Commission, pursuant to the Federal Hazardous Substances Act, a substance presents a hazard warranting label warnings if it meets the following requirements:

⁹ See March 13, 2017 Comments at 1 n.1.

¹⁰ Scope Document, p.16.

¹¹ See *id.*, p.17.

¹² ECHA Registration Dossier, CAS 81-33-4, <https://echa.europa.eu/registration-dossier/registered-dossier/10330>.

¹³ See March 13, 2017 Comments, p.3.

To require labeling, a product must first be toxic, corrosive, flammable or combustible, an irritant, or a strong sensitizer, or it must generate pressure through decomposition, heat, or other means. Second, the product must have the potential to cause substantial personal injury or substantial illness during or as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.¹⁴

While formulated products containing ingredients other than C.I. Pigment Violet 29 can pose a hazard based on the attributes of those ingredients, C.I. Pigment Violet 29 does not itself pose a hazard and does not meet these requirements. It is, therefore, inappropriate for EPA to describe C.I. Pigment Violet 29 as regulated under the Federal Hazardous Substances Act¹⁵ due to “whole products” containing formulated ingredients other than C.I. Pigment Violet 29 with no relevance to the assessment of C.I. Pigment Violet 29.

In the Scope Document under the topic “Laws and Regulations in Other Countries and International Treaties or Agreements,”¹⁶ the list of international chemical inventories which incorporate C.I. Pigment Violet 29 should include the following nations, which were omitted: China, Korea, New Zealand, Philippines, Taiwan, and Vietnam.

Although the Scope Document indicates that C.I. Pigment Violet 29 is registered on the Canadian Domestic Substances List (“DSL”) pursuant to the Canadian Environmental Protection Act of 1999, the Scope Document does not show the current DSL status of C.I. Pigment Violet 29. It should. The current DSL status of C.I. Pigment Violet 29 is as follows:

CAS RN: 81-33-4
Name: ANTHRA[2,1,9-DEF:6,5,10-D'E'F'] DIISOQUINOLINE-
1,3,8,10(2H,9H)-TETRONE
Substance category: OR
Meets CEPA criteria: No
Meets human health criteria: No
Meets environmental criteria: No
Persistent: Yes
Bioaccumulative: No
Inherently toxic to aquatic organisms: No

The only information which CPMA has received from EPA to explain the reason for selecting CI Pigment Violet 29 for the EPA Work Plan in 2012, and subsequently identifying it for analysis in the first ten substances under the Amended TSCA, referred to an aquatic toxicity citation in the

¹⁴ See <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/FHSARrequirements>.

¹⁵ See Scope Document, p.12, Appendix A 1.

¹⁶ Scope Document, p.12.

Canadian Categorization of the DSL.¹⁷ As is obvious from the above, however, the categorization in Canada did *not* conclude that C.I. Pigment Violet 29 presents an aquatic hazard.

D. Foreseeable Uses Which Will Be the Subject of the Assessment

Since there is no known hazard from exposure to C.I. Pigment Violet 29, there is no reason to engage in extensive analysis of the reasonably foreseeable commercial uses for C.I. Pigment Violet 29. Nonetheless, the overall summary of production and uses based upon comments and information provided on behalf of CPMA by the Sun Chemical Corporation (“Sun Chemical”) appears to be accurately reflected in the Scope Document. Sun Chemical is the only entity meeting the requirements for submitting a Chemical Data Report. Only 10% of C.I. Pigment Violet 29 production in the United States is sold for commercial purposes, while 90% of C.I. Pigment Violet 29 production in the United States is used for production of other perylene pigments.²¹

EPA identifies professional quality watercolors and acrylic artist paints as a potential consumer exposure. As indicated by the Scope Document and CPMA’s March 13, 2017 Comments, the use of C.I. Pigment Violet 29 in the production of professional artist paint is at most a very limited use of the pigment, representing less than 1% of sales. Pigments encapsulated in professional artist paint resin, do not generate consumer exposure to the pigment.

CPMA understands that EPA is in dialogue with several of its member companies regarding the possibility of worker exposure in the manufacture of C.I. Pigment Violet 29. CPMA and its members do not possess information regarding worker or consumer exposures to downstream products containing the pigment (e.g., coatings, plastics and artist paints). CPMA has contacted associations representing those industries to advise them of EPA’s interest in such information. However, as noted above, given the absence of any toxicity exhibited by C.I. Pigment Violet 29, EPA has no need to develop such exposure information.

E. The Bibliography

The references cited in the Bibliography supporting the Scope Document are not relevant to C.I. Pigment Violet 29 and do not identify a hazard warranting further risk assessment. EPA claims in the Scope Document that it has undertaken computer database searches for citations to additional studies that are not cited in the Scope Document. A review of the references listed in the bibliography indicates that the vast majority have no relevance to pigments, and the few that are relevant to pigments identify other, non-perylene pigments, such as azo pigments or diarylide pigments, which, again, have no relevance to perylene pigments.

¹⁷ See Email from Ms. Leslie Cronkhite EPA to J. Lawrence Robinson (May 24, 2012). ²¹ Scope Document, p.19.

For example, the EPA Bibliography cites the following references:

“OECD (Organisation for Economic Co-operation and Development). (2003). SIDS Initial Assessment Report for SIAM 16: C.I. Pigment Yellow 12; Butanamide, 2,2'[(3,3'-dichloro [1,1'-biphenyl]-4,4'diyl) bis (azo)]bis[3-oxy-N- phenyl-; C.I. Pigment Yellow 13; Butanamide, 2,2'[(3,3'-dichloro[1,1'-biphenyl]-4,4'diyl)bis(azo)]bis[N-(2,4-dimethylphenyl)-3-oxo-; C.I. Pigment Yellow 83; Butanamide, 2,2'[(3,3'- dichloro[1,1'-biphenyl]- 4,4'diyl)bis(azo)] bis [N-(4-chloro-2,5-dimethoxyphenyl)-3-oxo. Paris, France: Organisation for Economic Cooperation and Development”. <http://webnet.oecd.org/hpv/ui/handler.axd?id=7450284D-EACC-4DD9-B1CB-24FAE5914EED>

Diarylide pigments have no structural resemblance to perylene pigments. This OECD study is not germane to the evaluation of C.I. Pigment Violet 29 or perylene pigments, all of which lack an aromatic amine or an azo bond, while containing a fused aromatic ring system and an imide (2 of them), which are lacking in the diarylide pigments.

III. Conclusion

C.I. Pigment Violet 29 does not present a health or ecological hazard warranting further analysis in the problem formulation phase of EPA's risk evaluation process under amended TSCA. Had C.I. Pigment Violet 29 undergone the prioritization process, EPA would have recognized that C.I. Pigment Violet 29 is not likely to present an unreasonable risk of harm to health or the environment, and thus should be classified as a low priority for further evaluation. EPA can and should reach that conclusion now, and focus its efforts and resources on other substances which may pose unreasonable risk.

Sincerely,

A handwritten signature in dark ink, appearing to read "David J. Wawer". The signature is fluid and cursive, with the first name "David" and last name "Wawer" clearly distinguishable.

David Wawer
Executive Director